



## Information Sheet 3

### ***Dioxin Reassessment Process: EPA is Moving Toward Completion of the Dioxin Reassessment***

The U.S. Environmental Protection Agency's (EPA) is in the final stages of completing its reassessment of dioxin exposure and human health effects entitled, "*Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds.*" The Agency expects that the completed reassessment will be available before the end of the year. The purpose of this updated *information sheet* is to describe briefly the process that EPA has used in developing the final reassessment and to apprise the public about the remaining steps needed to bring this complex scientific activity to a close.

**BACKGROUND:** In April 1991, EPA announced that it would conduct a scientific reassessment of the health risks of exposure to dioxin and dioxin-like compounds. EPA began this task in light of significant advances in our scientific understanding of mechanisms of dioxin toxicity, significant new studies of dioxin carcinogenic potential in humans and increased evidence of other adverse health effects. EPA has worked to make each phase of the dioxin reassessment an open and participatory process. These efforts have included the involvement of outside scientists as principal authors of several chapters, frequent public meetings to report progress and take public comment, and publication of early drafts for public comment and peer review. Early in the reassessment process, EPA held public meetings (1991 and 1992) to inform the public of the Agency's plans and activities for the reassessment, to hear and receive public comments and reviews of the proposed plans, and to receive any current, scientifically relevant information. In 1992 and 1993, the Agency convened three peer-review workshops to review early drafts of the reassessment chapters. The Agency remains committed to an open and participatory process as it approaches the final reassessment.

**STRUCTURE OF FINAL REASSESSMENT DOCUMENT:** The final dioxin reassessment will consist of three parts. *Part I. Estimating Exposure to Dioxin-Like Compounds* will include three volumes that focus on sources, levels of dioxin-like compounds in environmental media, and human exposures. *Part II. Health Assessment for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* will consist of two volumes that include information on critical human health end points, mode of action, pharmacokinetics, dose-response, and TEFs. Part II will have nine chapters. *Part III. Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds* will be a stand alone document. In this part, key findings pertinent to understanding the potential hazards and risks of dioxins are described and integrated, including a discussion of all important assumptions and uncertainties.

#### **1994 PUBLIC REVIEW DRAFT AND 1995 SCIENCE ADVISORY BOARD (SAB) REVIEW:**

In September 1994, EPA released the external review drafts of the health effects and exposure documents which amounted to over 2,200 pages. EPA took public comment on the drafts, followed by SAB review of the draft dioxin reassessment in May 1995. The SAB's report was received in Fall of that year. In its

report to the Agency, the SAB responded favorably to most of the reassessment, but recommended revision of two key sections. The SAB recommended that Chapter 8: Dose-Response Modeling for TCDD and the Risk Characterization document, be revised. Further, it recommended development of an additional document that would focus on the toxicity equivalent factors (TEFs) for dioxin and dioxin-like compounds. In addition to these substantive recommendations, the SAB suggested that the redrafting process include broader participation of outside scientists from both public and private sectors. They also requested that the two redrafted chapters and the new TEF chapter be submitted to independent external peer review, before being returned to the SAB for re-review. With respect to Chapters 1-7 of the health document and the full exposure reassessment document, the SAB accepted these sections. It suggested that they be updated to address public and SAB comments and to incorporate new scientific data, but stated that further review of these sections by that SAB was not needed.

**POST-SAB REVISION PROCESS:** After receipt of the SAB's 1995 report, the Agency worked with over 40 stakeholders from the private and public sectors, representing environmental, industry, academic, state, and other public interest and public health communities, on next steps and to gather input on possible approaches for conducting the revision process. The Agency has tried to keep these individuals apprised of reassessment activities at critical points in the revision process. These stakeholder groups have been important avenues of public input as the revised dioxin reassessment sections have been made available for public comment. The three draft sections recommended for review by the SAB were:

**Part II. Chapter 8: Dose-Response Modeling** <sup>o</sup> This chapter was revised using a writing team process. The writing team was composed of a dozen leading scientific experts in fields related to dioxin health effects and quantitative risk assessment. These experts came from a wide range of public and private organizations, as well as academia. The draft Chapter 8 underwent public comment and external peer review in March 1997. A writing team developed the draft final chapter based on the peer review and public comments and any relevant new scientific data, in January 2000.

**Part II. Chapter 9: Toxicity Equivalence Factors (TEF) for Dioxin and Related Compounds**

<sup>o</sup> This new document was developed as a result of a recommendation from the SAB to gather in one place the discussion and scientific information on the complex issue and use of TEFs for dioxin and dioxin-like compounds. The draft was developed by an internal writing team with assistance from international experts.

**Part III. Integrated Summary and Risk Characterization** <sup>o</sup> This section, formerly identified as Chapter 9, also followed the writing team process. A preliminary revised draft was developed by a writing group made up of scientists from a wide range of public and private organizations, as well as academia, and was reviewed by the stakeholders. This preliminary draft was used as the framework for an extensively revised document developed by a small internal EPA writing group.

**RECENT EVENTS:**

**July 25 and 26, 2000** <sup>o</sup> **External Peer Review:** On July 25 and 26, a two-day external peer review

workshop was conducted in Washington, DC. This peer review meeting was for the purpose of reviewing the draft *TEF chapter* and draft *Part III. Integrated Summary and Risk Characterization*. The Agency used a private contractor to plan and conduct the meeting and to identify and secure the services of independent expert scientists as peer reviewers. The public was

invited to attend the peer review meeting as observers and a limited amount of time was made available for comments by the observers. General view was that addition of the TEF chapter was beneficial and added to the strength of the reassessment and that the characterization document was much improved over the previous draft. Major points of discussion were the following key dioxin science issues: the characterization of cancer risk, how to extrapolate between animals and humans, quantitative estimation of cancer risk, noncancer effects seen close to background exposures, and children's risk. The Agency used the peer review report, the public comments made at the meeting, and the public comments submitted as a result of the public comment period announced in the Federal Register on June 12, 2000, to revise the two documents in preparation for review by the SAB.

**September 25, 2000 ° Revised Drafts Sent to SAB for Final Review:** Based upon comments received from the peer review panel and during the public comment period, the dose-response modeling chapter, the TEF chapter, and the Integrated Summary and Risk Characterization were revised, as appropriate, and formally submitted to the SAB on September 25. An October 4 Federal Register notice announced the public availability of the SAB review drafts and the dates of the SAB's review meeting.

**November 1 and 2, 2000 ° SAB Dioxin Reassessment Review Subcommittee Meeting:** The SAB's Dioxin Reassessment Review Subcommittee (DRRS) met on November 1<sup>st</sup> and 2<sup>nd</sup> to review the draft "*Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds.*" The focus of the review was on three draft documents: *Part II. Chapter 8: Dose-Response Modeling*; *Part II. Chapter 9: TEFs for Dioxin and Related Compounds*; and *Part III. Integrated Summary and Risk Characterization*. After in depth discussions of key science and assessment issues in the draft documents, the review panel, made up of SAB members and consultants, approved the draft report saying they were confident the Agency could address their review comments prior to finalizing the reassessment and that they did not need to see the document again. The two day meeting included over 40 public comments. The draft DRRS review report was submitted to the SAB's Executive Committee for review and approval.

**May 15, 2001 ° SAB Executive Committee Review Meeting:** After a public meeting on May 15, the SAB's Executive Committee endorsed a review report of the draft dioxin reassessment contingent upon changes to address some of the differing scientific opinions raised in the review report. On or about June 1, the SAB plans to forward its review of the Agency's draft dioxin reassessment to the Administrator. This represents the next critical step toward finalization of the Agency's comprehensive reassessment of the risks from dioxin, including identifying sources of dioxin to the environment.

**NEXT STEPS:** The following major steps are being planned to complete the EPA's dioxin reassessment:

**June/July 2001 ° Final Revision of Reassessment Documents:** Once the SAB report has been forwarded to the Administrator, EPA will complete the revisions of the draft dioxin reassessment in response to SAB recommendations and public comments. The Agency will work to complete final revisions to Part I. Estimated Exposure to Dioxin-Like Compounds, Part II. Health Assessment of 2,3,7,8-TCDD and Related Compounds, including Chapters 8 and 9, and Part III. Integrated Summary and Risk Characterization for 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds.

**Fall 2001 <sup>o</sup> Anticipated Public Release of Completed Dioxin Reassessment:** The Agency intends to complete its comprehensive reassessment of dioxin exposure and human health effects entitled, “*Exposure and Human Health Reassessment of 2,3,7,8-Tetrachlorodibenzo-p-Dioxin (TCDD) and Related Compounds.*” This release would be accompanied by an announcement to the public on how to obtain copies of the complete and final documents.

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